

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/834,312	04/13/01	ILLUM	L 8567-600US (

000576

HM12/0829

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EXAMINER

FUBARA, B

ART UNIT

PAPER NUMBER

1615 S

DATE MAILED: 08/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/834,312	ILLUM ET AL.
	Examiner Blessing M. Fubara	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4,9-20 and 22 is/are rejected.
- 7) Claim(s) 5--8 and 21 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                           | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 . | 6) <input type="checkbox"/> Other: _____ .                                   |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 101*

1. Claims 15-19 provide for the use of a composition comprising fexofenadine or pharmaceutically acceptable salt and pharmaceutical excipient, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 15-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

#### Applicants' Invention:

The claimed invention is directed to a composition comprising fexofenadine or pharmaceutically acceptable salt and a pharmaceutical excipient. Applicants claim a broad generic invention comprising fexofenadine antihistamine and an excipient. The route of administration is not critical in a composition claim and what the excipient does is not critical in a composition claim. The prior art only has to teach the composition to meet the limitations of the claims. The language of comprising does not exclude other ingredients/additives/carriers/excipients that the invention may be silent on in the claims. The method claims recite generic administration of a composition/formulation/dosage from to a patient in need thereof.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1-4, 9-14, 20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cupps et al. (US 5,691,370).

Cupps discloses a pharmaceutical comprising terfenadine or terfenadine carboxylate, carriers lactose, sucrose, starches, propylene glycol, glycerin and mannitol and suspending agents such as tragacanth and sodium alginate (column 16, line 23 to column 18 line 48 and claim 1). Cupps specifically teaches intranasal and intraocular dosage form and discloses that topical intraocular composition comprises poloxamer vehicles (column 18, lines 13-48). The teachings of Cupps meet the limitations of the claims.

4. Claims 1-3, 14 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al. (US 6,120,803).

Wong discloses a composition comprising fexofenadine, surfactants, carriers and excipients (column 5, lines 13-19, 44-49 and 56-61, column 6, lines 13-25, column 17, lines 22-38 and claims 4 and 6). The teachings of Wong meet the limitations of the claims.

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5. Claims 1-3, 12-14 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Lech (US 6,027,746).

Lech discloses a pharmaceutical composition comprising fexofenadine (column 4, line 7), excipients (column 4, lines 52-56) and poloxamer 407 (column 6, lines 35-61). See also abstract and claims 1-8. The teachings of Lech meet the limitations of the claims.

6. Claims 1-4, 12-14 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Ahlgren et al. (US 6,117,452).

Ahlgren discloses a composition comprising fexofenadine, excipients and surfactants such as Poloxamers, Tweens and Spans (column 2, lines 7-65, column 6, lines 9-38, and claims 3, 4, 8, 13 and 21). Ahlgren teaches that the composition is formulated into tablets, pills, capsules, troches and liquid suspension and specifically states that transdermal, buccal and nasal dosages are contemplated (column 6, lines 28-30). The teachings of Ahlgren meet the limitations of the claims.

7. Claims 1-3, 9-11, 14, 20 and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by pages 1189 to 1190 of the 1998 physician desk reference.

The 1998 physician desk reference discloses a capsule dosage form of fexofenadine (ALLEGRA<sup>TM</sup>). The dosage form comprises excipients and other additives such as iron oxide, gelatin, silicon dioxide, titanium dioxide and sodium lauryl sulfate. See pages 1189-1190, 1998 PDR. This publication on ALLRGRA meets the limitations of the claims.

8. Claims 5-8 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Observation (minor): Claim is capitalized in claim 5 and is the plural form of the word defining a singular object.

9. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara  
August 25, 2001



THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600